UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,174	02/26/2004	Michel Franz	09997.0087US01	9902

23552 7590 12/21/2005

MERCHANT & GOULD PC
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

EXAMINER	
SILVERMAN, ERIC E	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 12/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/789,174	FRANZ, MICHEL	
	Examiner	Art Unit	
	Eric E. Silverman, PhD	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-15 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-15 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 5-27-05, 2-26-04, 11-12-04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of the following documents is hereby acknowledged: Two (2) Information Disclosure Statements filed 27 May 2005 and 12 November 2004,Two (2) Preliminary Amendments filed 26 February2004 and 1 June 2004.

Claims 1 – 15 are pending in this application.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in the European Patent Office on 9 January 2004. It is noted, however, that applicant has not filed a certified copy of the European application as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 5, and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a written description rejection**.

With regard to claim 3, the claim recites, in part "suitable salts, esters, amides, prodrugs, or analogues thereof", in reference to the NSAID's mentioned in the claim.

However, there is no description in the specification of compositions containing any suitable ester, amide, prodrug, or analogue of these compounds. Accordingly, a person of skill in the art would not recognize that the applicants actually had possession of a composition comprising a suitable ester, amide, prodrug, or analogue.

With regard to claim 5, the claim recites in part "analogues of derivatives thereof", in reference to the prostaglandins recited in the claim. However, there is no description in the specification of compositions containing any analogue or any derivative of these materials. Accordingly, a person of skill in the art would not recognize that the applicants actually had possession of a composition comprising an "analogue or derivative thereof".

With regard to claim 15, the claim recites a packaging to minimize oxygen permeation. However, the specification gives neither a description of such a packaging, nor any example of what such a packaging is made from so that the packaging may be useful in the composition claimed. As such, the person of ordinary skill in the art would doubt that the applicant actually had possession of such a packaging composition as of the filing date of the application. In addition, the specification does not disclose a "gastroprotective drug analogue medicament". Accordingly the artisan would not reasonably understand that applicant was in possession of a composition comprising the same as of the filing date of the invention.

Claim 1 is rejected as being the independent claim upon which the rejected claims 3, 5, and 15 depend.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 5, 6, and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to claim 3, this claim recites "suitable salts, esters, amides, prodrugs, or analogues thereof". It is unclear what the materials must be suitable for. In addition as a corollary, is unclear as to what differentiates a suitable ester, amide, or prodrug or analogue from an unsuitable one. Although the specification gives non-limiting examples of suitable analogues, a person of ordinary skill in the art would not be able to recognize if an analogue not mentioned, or if any given ester, amide or produrug is suitable or unsuitable. Accordingly, the metes and bounds of the claim would not be clear to the artisan.

With regard to claim 4, this claim is rejected for depending on claim 3, and thus incorporating all of the indefinite limitations of claim 3.

With regard to claim 5, the claim recites "analogues or derivatives thereof". The artisan would not know what is included as an analog or derivative of the named materials. Accordingly, it would be impossible for a person of ordinary skill in the art to understand the metes and bounds of this claim.

With regard to claim 15, it is unclear what is meant by "minimize oxygen permeation". The artisan would not know how much oxygen may permeate the claimed packaging composition and for said permeation to be "minimized", as required by this

claim. In addition, the claim does not define, and the specification provides no guidance, as to what is meant by "gastroprotective drug analogue medicament". The artisan would not understand the term "drug analogue medicament", as such is not a term commonly used in the art. Accordingly, it would be impossible for a person of ordinary skill in the art to understand the metes and bounds of this claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 – 9 and 11 – 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Gimet et al., US 5,601,843, of record.

Gimet discloses a core-mantle tablet formulation (abstract). The core comprises a NSAID, which is diclofenac in some specified embodiments, microcrystalline cellulose (a cellulose based polymer), and magnesium sterate (a lipidic material), the mantle comprises a prostaglandin, which is mioprostol in some specific embodiments, dispersed in HMPC, wherein there is present a coating on the core which separates the

core from the mantle, said coating containing no active agents (Examples 2 – 9). The NSAID is not specifically mentioned to be for sustained release, and mioprostol is not specifically mentioned to be for immediate release, but the same compositions will necessarily have the same properties. With regard to the limitation of claim 9 that the first region have several units, there is no requirement that each unit contain a therapeutically effective amount of NSAID, and as such the "first region" of this claim could be the core and the coating on the core, which would comprise at least two units, said units comprising a therapeutically effective amount of the drug. With regard to claims 12 and 13, it is disclosed that there are several advantages to the composition, for instance, that the prostaglandin prevents NSAID induced ulcers (paragraph bridging col.'s 11 and 12). For this information to be known, it is inherent that the composition was administered, as required by instant claims. With regard to claim 14, since the two drugs in the composition have different release profiles (since one is in the mantle and the other in the core), the composition could be called a dual release composition. The recitation of "allowing a once a day or twice a day dosing to humans" is a future intended use, and is given no patentable weight in composition claims.

Claims 1 – 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Cheburkar et al., US .5,213,807.

Chemburker discloses a tri-layer pharmaceutical tablet wherein the core comprises ibuprofen and stearic acid, stearic acid being a lipidic material, the core being coated by a coating that contains no active agent, and a mantle covering said coating

wherein the mantle comrprises misoprostol and hydroxypropylmethyl cellulose. (Examples 1 – 3). With regard to claim 9, the "several units" of the first region could be interpreted as the core and coating on the core, and the second region could be interpreted as the mantle.

Claims 1 – 6 and 8 – 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Ouali et al., US 6,183,779 B1.

Ouali discloses a pharmaceutical dosage form comprising a three regions, where the first region comprises granules, said granules comprising diclofenac and microcrystalline cellulose (Examples 3 and 4), the second region comprises an enteric coating which surrounds the abovementioned granules, and the third region comprises a misoprostol-HMPC complex (Examples 1 and 2). A capsule dosage form is made by filling a capsule with these three regions. Also, a tablet is made by compressing the regions into a dual-layer tablet (Examples 5 and 6, drawings, and descriptions thereof, also claims 1 – 26). Ouali also discloses a method for treating a patient by administering the pharmaceutical dosage form (claims 27 – 35). Ouali also notes that the method may involve twice daily administration (claims 28, 30, and 32)

Claims 1 – 9 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Sherman, US 6,656,503 B1.

Sherman discloses a pharmaceutical composition comprising a core and a film coating, wherein the core comprises a NSAID and the film coating comprises a polymer

and misoprostol (abstract). The film of Sherman is equivalent to the mantle of instant claims. In one embodiment (example 1), the core comprises diclofenac, microcrystalline cellulose (a cellulose based polymer) and magnesium stearate (a lipidic material). The core is then coated with an enteric coating, which can be interpreted as the third region comprising no active material in instant claims that require the same, and the outer coating, or mantle, comprises HPMC and misoprostol. The first region of instant claim 9 could be considered to be comprised of two units, said units being the core of Sherman and the enteric coating of Sherman.

Claims 1 – 6, and 9 – 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Woolfe et al., US 2002/0054908, of record.

Woolfe discloses a pharmaceutical dosage form including a mixture of a delayed-release NSAID and a mixture containing a prostaglandin (abstract). The composition is, in one embodiment, a capsule. In this embodiment, the capsule is filled with delayed release ketoprefen beads, misoprestol diluted with HPMC, and other excipients (Example 1). The delayed release beads comprise the NSAID and Eudragit, the latter being a methacrylate copolymer (Example 3). A multiple unit tablet is also disclosed (Example 4).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12 – 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woolfe et al, US 2002/0054908, of record.

Some of the teachings of Woolfe are discussed above. Wolfe also teaches that the NSAIDs are used in the treatment of osteoarthritis or rheumatoid arthritis (paragraph 0002).

Woolfe does not teach a method of administering dosage forms. Nonetheless, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to administer the dosage forms to a person suffering from osteoarthritis or rheumatoid arthritis, since this is the intended use of the active agents in Woolfe's compositions. It is generally obvious to use a composition for its intended purpose. The expected result would be a method of administering the composition of Woolfe.

Claims 12 – 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chemburker or Sherman, in either case in view of Ouali.

The teachings of Chembuker and Sherman are discussed above.

Neither teaches a method of administering a dosage form.

The teachings of Ouali are discussed above. Particularly important is the teaching of a method of administration of a dosage form comprising a NSAID and a prostaglandin.

Thus, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to administer either the composition of Chembuker or that of

Sherman using the method of Ouali. The motivation to do so comes from Ouali, who teaches a method of using a composition with the same active agents as that of Chembuker and Sherman. Accordingly, the artisan would expect a reasonable expectation of success in using the compositions of Chembuker and Sherman in the same fashion as those of Ouali are used. The expected result would be a method of administering the composition of Chembuker or that of Sherman according to Ouali.

Conclusion

No claims are allowed. No claims are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Eric E. Silverman, PhD
Art Unit 1615

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600